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EXAMINER

LAMM, MARINA

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 26

Application Number: 09/780,060
Filing Date: February 09, 2001
Appellant(s): KITSON ET AL.

Marina T. Larson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/14/03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 4, 5, 6, 7 and 15 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,916,578 KAWADA et al. 6-1999

"Concise Encyclopedia Chemistry", translated and revised by Mary Eagleson, 1994,
pp. 599-600

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-3, 6-9 and 14-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kawada et al. (US 5,916,578).

Kawada et al. teach skin treatment compositions containing a liquid crystal phase containing a combination of a compound from ceramide family, cholesterol and a fatty acid (e.g. palmitic acid) in the claimed proportions. See col. 1, lines 5-10; col. 15, Compositions 26 and 27. The lipid compositions of Kawada et al. may be mixed with water. See col. 5, lines 9-15; col. 15, Compositions 26 and 27. With respect to Claims 6, 7 and 15, when the combination of lipids is mixed with aqueous phase by shaking the suspension, the liposomes that are formed are inherently multilamellar and have diameters from 100 to 3000 nm. See col. 17, lines 1-5 and "Concise Encyclopedia Chemistry", p. 599. With respect to the limitation "crystalline lamellar phase" in Claims 1 and 8, this limitation is inherent in the prior art. If the composition of the instant claims adopt a crystalline lamellar phase either upon application to the skin or after the penetration into the stratum corneum, the compositions of Kawada et al. will inherently behave the same because they contain the same ingredients as the claimed compositions. Under the doctrine of "inherency", prior art may anticipate a claim if it "inherently" possesses all of the elements of the claimed invention, even if it "did not fully

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appreciate the uses, purposes, or properties of the product or process' created. General Electric Company v. Hoechst Celanese Corp., 740 F. Supp. 305, 312 (D. Del. 1990). With respect to Claims 14, 16, 17, 18 and 19, the compositions 26 and 27 exemplified in col. 15, are free from all listed ingredients.

2. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawada et al.

Kawada et al. applied as above. With respect to Claims 4 and 5, Kawada et al. do not teach using bovine brain ceramide or ceramide 2. however, Kawada et al. teach that their composition "is used for a cosmetic or pharmaceutical product, it gives the same effect as a known natural ceramide extracted from bovine brain." See col. 11, lines 64-67. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use bovine brain ceramide or any other ceramide used in cosmetic compositions for compositions of Kawada et al. with a reasonable expectation of deriving the same cosmetic effect as set forth in the reference.

(11) Response to Argument

The Applicant argues that the compositions of Kawada et al., while containing the same ingredients as the claimed compositions, do not inherently possess the same properties as the claimed compositions. In particular, the Applicant argues that the compositions 26 and 27 of Kawada et al. (see col. 15), in addition to the claimed ingredients (i.e. cholesterol and palmitic acid), both contain materials (i.e. cholesteryl sodium sulfate and 2-oleylaminooctadecane-1,3-diol) which are "not included in any of Applicants' compositions." See p. 4 of the Brief. This statement is not completely accurate because 2-oleylaminooctadecane-1,3-diol of Kawada et

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al. is a ceramide which is within the scope of at least Claim 3 of the instant invention. The Applicant argues that the Declaration under Rule 132 (paper #16) directly refutes the Examiner's position by the following statements: (1) cholesteryl sodium sulfate of Kawada's compositions "does not crystallize to the same extent as cholesterol"; (2) oleylaminoctadecane-1,3-diol of Kawada's compositions is "sterically unlikely to crystallize"; and (3) the compositions of Kawada are "hydrated with a very small amount of water" unlike the claimed compositions which are "aqueous formulations." See pp. 4-5 of the Brief. In response, the Applicant's statement that cholesteryl sodium sulfate "does not crystallize to the same extent as cholesterol" is not sufficiently definite to support an argument for the absence of crystallization. Further, the Applicant's statement that oleylaminoctadecane-1,3-diol is "sterically unlikely to crystallize" also not sufficiently definite, nor supported by scientific data to establish a fact of non-crystallization. Lastly, the claim limitation of "aqueous formulations" merely requires the presence of water. There is no claim requirement that water be present in sufficient amounts to be a carrier. Further, it is noted that the lipid compositions of Kawada et al. can be incorporated into aqueous carrier. See col. 17-18. Finally, the Applicant argues that "there is specific evidence in this case that the compositions of Kawada do not meet the limitations of the present claims concerning the formation of a crystalline phase." "Kawada et al. actually provide data to show that their liquid crystals do *not* crystallize (col. 14, lines 18-19; column 13, lines 51-58)." (emphasis in original) See p. 5 of the Brief. In response, it is noted that the Kawada's compositions in the form of lamellar liquid crystal structures did not crystallize *in vitro*. Similarly, the claimed compositions, which contain lipids "in a non-crystalline lamellar array" (e.g. liquid crystalline structure) crystallize only when applied to

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the skin (or after penetration into the stratum corneum). See instant Claims 1, 8 and 9. The Applicant did not provide any evidence that the compositions of Kawada et al. will not form a crystalline phase *upon application to the skin*. Since the compositions of Kawada et al. contain the same combination of lipids, in the same amounts and proportions, form the same non-crystalline lamellar structure in vitro and produce the same cosmetic effect as the claimed compositions, it is the Examiner's position that the recited property "adopt a crystalline lamellar phase upon application to mammalian skin" is inherently possessed by the compositions of Kawada et al.

With respect to Claims 6, 7 and 15, the Applicant argues that "Kawada does not teach that liposomes form. Kawada does not teach that lipid particles of any particular type or size form." See p. 6 of the Brief. In response, Kawada et al. teach formation of "small oily micelles dispersed in the aqueous phase" when hydrated liquid crystals containing ceramide, cholesterol and fatty acid are mixed with the oily phase ingredients by vigorously stirring with a homogenizer. See col. 16, lines 64-67; col. 17, lines 1-5. The "oily micelles" of Kawada are inherently liposomes because they contain the same ingredients, i.e. ceramide, cholesterol and fatty acid as the claimed lipid compositions. The supplemental reference ("Concise Encyclopedia Chemistry") was used to show that the claimed size of liposomes will be inherent to those liposomes obtained by stirring.

With respect to Claims 4 and 5, the Applicant argues that there is no motivation to replace the ceramide in the Kawada composition with bovine brain ceramide or ceramide 2. In response, Kawada et al. teaches that their compositions give "the same effect as a known natural ceramide extracted from bovine brain". See col. 11, lines 64-67. Moreover, the lipid

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compositions of Kawada et al. have the same structure and are used in skin care compositions for the same purpose as the claimed composition, i.e. as skin or hair-protecting and moisture-retaining compositions. See col. 3, lines 8-18. Therefore, in the absence of some evidence of unexpected results due solely to the use of bovine brain ceramide or ceramide 2, it would have been obvious to one having ordinary skill in the art at the time of the invention to use any ceramide compounds vs. the claimed ceramides, because the prior art says that their ceramides are effective in skin/hair protective compositions. Therefore, there is a reasonable expectation of deriving the same cosmetic effect, i.e. skin or hair-protecting and moisture-retaining.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Examiner
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September 14, 2003

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